JC10 Rec'd PC TO 19 JUL 2005 PCT

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

n re the Application of: Tetsushi TAGUCHI et al.

Group Art Unit: Not yet assigned

Serial No.: 10/527,694

Examiner: Not yet assigned

Filed: March 11, 2005

Confirmation No.: Not yet assigned

For: BIOLOGICAL LOW-MOLECULAR WEIGHT DERIVATIVES

Attorney Docket Number: 052203

Customer Number: 38834

### SUBMISSION OF ENGLISH TRANSLATION OF IPER

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

July 19, 2005

Sir:

Submitted herewith is an English translation of the International Preliminary Examination Report for the above-identified U.S. patent application. Please note that the cited references of the International Preliminary Examination Report were previously filed with the Information Disclosure Statement on March 11, 2005.

If any additional fees are due in connection with this submission, please charge our Deposit Account No. 50-2866.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP

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Enclosure: Form PCT/IB/338

From the INTERNAT AL BUREAU

# PCT

NOTIFICATION OF TRANSMITTAL OF COPIES OF TRANSLATION OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 72.2)

To:

NISHI, Yoshiyuki Nishi Patent Office Suite 211, 26-32, Nakahara 4-chome Isogo-ku Yokohama-shi, Kanagawa 235-0036 JAPON

Date of mailing (day/month/year) 26 May 2005 (26.05.2005)	
Applicant's or agent's file reference 03-W-19	IMPORTANT NOTIFICATION
International application No. PCT/JP2003/011669	International filing date (day/month/year) 11 September 2003 (11.09.2003)
Applicant NATIONAL IN	ISTITUTE FOR MATERIALS SCIENCE et al

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

CA, CN, EP

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

US

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

Masashi Honda

Facsimile No.+41 22 740 14 35

Facsimile No.+41 22 338 70 10

Form PCT/IB/338 (July 1996)



Translation

## PATENT COOPERATION TREA



# **PCT**

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03-W-19	FOR FURTHER A	ACTION	See Form PCT/IPEA/416			
International application No.	International filing d	ate (day/month/year)	Priority date (day/month/year)			
PCT/JP2003/011669	11 September 2	003 (11.09.2003)	11 September 2002 (11.09.2002)			
International Patent Classification (IPC) or na C07D 207/46, C08J 3/24 // A61I	ational classification a 27/18, 26/00	and IPC				
Applicant						
NATIONA	AL INSTITUTE F	OR MATERIALS	SCIENCE			
This report is the international prelim	.:					
Authority under Article 35 and transi	mary examination remitted to the applican	port, established by this taccording to Article 36	International Preliminary Examining			
2. This REPORT consists of a total of 4 sheets, including this cover sheet.						
3. This report is also accompanied by A	NNEXES, comprisin	g:				
a. (sent to the applicant and t	to the International B	ureau) a total of3	sheets, as follows:			
sheets of the descr and/or sheets cont Administrative Ins	aining rectifications a	drawings which have be uthorized by this Author	en amended and are the basis of this report rity (see Rule 70.16 and Section 607 of the			
sheets which super beyond the disclos Supplemental Box	sure in the internation	ut which this Authority al application as filed, a	considers contain an amendment that goes is indicated in item 4 of Box No. I and the			
		total of (indicate tym	e and number of electronic carrier(s))			
	, conta	ining a sequence listing	g and/or tables related thereto, in computer Sequence Listing (see Section 802 of the			
4. This report contains indications relati	ng to the following it	ems:				
Box No. I Basis of the rep	oort					
Box No. II Priority						
Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability						
Box No. IV Lack of unity of invention						
Box No. V Reasoned states	nent under Article 35	(2) with regard to novelt	y, inventive step or industrial applicability;			
citations and explanations supporting such statement  Box No. VI Certain documents cited						
Box No. VIII Certain observations on the international application						
Date of submission of the demand		Date of completion of	this report			
12 April 2004 (12.04.2004)		01 Oc	tober 2004 (01.10.2004)			
Name and mailing address of the IPEA/JP		Authorized officer				
Facsimile No.		Telephone No.				

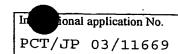


International application No.

PCT/JP2003/011669

Box No	. I	Basis of the report	
1. With other	regard	to the language, this report is based on the international application in the lar	nguage in which it was filed, unless
	This whic	report is based on translations from the original language into the followin h is language of a translation furnished for the purpose of:	g language,
		international search (under Rules 12.3 and 23.1(b))	
		publication of the international application (under Rule 12.4)	
İ		international preliminary examination (under Rules 55.2 and/or 55.3)	
·			
jui iii.	re not	I to the elements of the international application, this report is based on the receiving Office in response to an invitation under Article 14 are referrannexed to this report):  attenuational application as originally filed/furnished	(replacement sheets which have been ed to in this report as "originally filed"
		escription:	
لكا	pages		
	pages		, as originally filed/furnished
	pages	received by this Audionity on	
	the cla		
	pages		
	pages	\$ 5-7	, as originally filed/furnished
	pages'	, as amended (tog	gether with any statement) under Article 19
	pages'		27 August 2004 (27.08.2004)
	tha da		
		awings:	•
	pages'		, as originally filed/furnished
	pages'	received by this Authority off	
		10001100 by this rituitority on	
	a sequ	ence listing and/or any related table(s) - see Supplemental Box Relating to Se	quence Listing.
3. 🔀	The ar	nendments have resulted in the cancellation of:	
		the description, pages	
		the claims, Nos. 2-3	
	H :	the drawings, sheets/figs	
	님 '	the sequence listing (specify):	
	Ш ;	any table(s) related to sequence listing (specify):	
	(Rule 7	eport has been established as if (some of) the amendments annexed to this resince they have been considered to go beyond the disclosure as filed, as 70.2(c)).  The description, pages	eport and listed below had not been indicated in the Supplemental Box
		<del></del>	
* If item	4 appl	ies, some or all of those sheets may be marked "superseded."	

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT



V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Statement			
Novelty (N)	Claims	4-11	YES
	Claims	1	NO
Inventive step (IS)	Claims	4-11	YES
	Claims	1	NO
Industrial applicability (IA)	Claims	1, 4-11	YES
	Claims		NO

#### 2. Citations and explanations

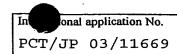
Document 1: JP 61-69759 A
Document 2: WO 01/91814 A

Document 3: Journal of Organic Chemistry, 1996, 61 (24),

pp. 8496-8499

The invention that is set forth in claim 1 lacks novelty in the light of document 3 cited in the international search report. Document 3 presents 2-tertbutyl 1,3-di-N-succinimidyl citrates, and indicates that citrate, which is to say citric acid, is present in the citric acid cycle. Thus, the abovementioned compounds that are presented in document 3 can be said to be citric acid derivatives to which two N-hydroxysuccinimide molecules have been fused by means of condensation; therefore, the compounds in the invention that is set forth in claim 1 are the same as the compounds that are presented in document 3. Meanwhile, in the written response the applicant asserts that "the low-molecular weight biological derivatives that are set forth in claim 1 are limited to 'low-molecular weight biological derivatives characterized in that after application within an organism, the derivatives are hydrolysed and react with biopolymers in the organism.'...Document 3 presents '2-tertbutyl 1,3-di-N-succinimidyl citrates,' but does not make

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT



any disclosures pertaining to the properties, the applications or the like thereof, and...does not make any disclosures pertaining to the technical characteristics of the invention that is set forth in claim 1..." However, the abovementioned compounds that are presented in document 3 are the same as the compounds in the invention that is set forth in claim 1; therefore, naturally, they must exhibit the property whereby "after application within an organism, the derivatives are hydrolysed and react with biopolymers in the organism."

The inventions that are set forth in claims 4-11 are not disclosed or suggested in documents 1-3 cited in the international search report; therefore, they are novel and involve an inventive step.